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LEADING ARTICLE

The Role of Angioplasty to Improve Inflow for Infrainguinal Bypasses

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Introduction

Patients with lower extremity ischaemic symptoms due to multilevel arteriosclerotic occlusive disease represent a frequently encountered and challenging problem.[1,2] Because of the high incidence of combined segment disease involving both inflow and outflow vessels, it is recognised that the adequacy of iliac arterial inflow must be carefully evaluated prior to any infrainguinal revascularisation procedure. It is widely accepted that the existence of haemodynamically significant proximal disease will lead to an unacceptable incidence of early failure of distal bypass, and this has led to the well-established principle in vascular surgery of initial correction of inflow disease prior to any distal vascular operation.

Although the majority of patients with multilevel disease will be benefited by proximal arterial reconstruction alone, it is well documented that adequate clinical improvement of ischaemic symptoms may not be achieved in 25–33% of patients.[3–7] A subsequent distal revascularisation procedure may be carried out, but requires reoperation in a scarred groin and exposes the patient to the inconvenience and potential risks of a second operative procedure. Similarly, in some patients with advanced ischaemic problems and extensive distal occlusive disease, it is clear that distal revascularisation will definitely be required to correct the principal haemodynamic impairment if the limb is to be salvaged. Even if associated iliac disease is only of moderate severity, it will still prohibit the surgeon from proceeding directly with the needed infrainguinal operation. In such circumstances, synchronous arterial reconstructions to correct both levels of disease must be considered. While this may be the optimal choice for good risk patients, such extensive combined reconstructions may result in considerable morbidity or mortality rates in these typically high-risk elderly patients afflicted with diffuse atherosclerosis and limited cardiopulmonary reserve.

For patients with relatively limited iliac occlusive disease, percutaneous transluminal angioplasty (PTA) is now well established as an effective alternative to conventional surgical treatment.[8–12] It would seem logical and potentially advantageous, therefore, to utilise iliac PTA to correct impaired inflow as a prelude to infrainguinal surgical revascularisation procedures in selected patients with multilevel disease. If appropriately employed, iliac PTA has the potential of establishing adequate inflow for a necessary distal surgical reconstruction in an expeditious and low morbidity manner. In such a treatment strategy, iliac PTA may be combined with a variety of outflow surgical procedures, including ipsilateral femoropopliteal and tibial bypasses, or profundaplasty by means of formal endarterectomy or patch angioplasty techniques. In addition, in patients with bilateral iliac disease, iliac PTA may be employed to correct inflow on the side with the least occlusive disease and thereby allow correction of more extensive contralateral iliac disease by means of a femorofemoral crossover graft.

However, many vascular surgeons remain reluctant to base a distal surgical procedure upon inflow established by iliac PTA for several reasons. First is concern that the adequacy of inflow improvement attained by PTA will not be sufficient to reliably

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support a distal graft. Second is the perception that iliac PTA may not provide a durable correction of iliac disease. Recurrence of impaired flow through the iliac system, due to either recurrent stenosis at the PTA site or development of new lesions at other sites in a diseased iliac segment treated by a focal measure such as PTA, would likely result in premature failure of distal grafts.

This review will examine available data in the literature on these issues, with particular emphasis on the clinical and haemodynamic success of the combined treatment modalities and the possible adverse effects of iliac re-stenosis on long-term function of distal surgical procedures. In addition, prerequisites and certain general principles important for successful application of combined iliac PTA and distal surgical revascularisation will be discussed.

Patient Selection

It is important to emphasise that the combination of iliac PTA and distal surgical revascularisation is appropriate for only a carefully selected subgroup of patients with multilevel disease. Typically, such patients will have relatively limited inflow lesions and more extensive infrainguinal disease. It is usually readily apparent that correction of distal disease needs to be the major focus of treatment to salvage the ischaemic limb or attain satisfactory relief of disabling claudication, yet the haemodynamic impairment of iliac inflow hinders proceeding directly with distal arterial reconstruction. It is also apparent in patients with such a pattern of disease that correction of only the modest proximal occlusive disease alone will not be likely to achieve a satisfactory clinical outcome.

Good preoperative arteriography is obviously of paramount importance in making such judgments. Biplane studies, supplemented with oblique pelvic views, are invaluable in identifying the extent and morphologic severity of both proximal and distal disease. In keeping with the well-established principles of lesions appropriate for PTA, iliac disease must be fairly localised. In virtually all reported series of combined procedures, iliac lesions undergoing PTA prior to distal operative procedures were stenoses (versus total occlusions), with diseased iliac segments less than 10 cm in length. It is also important to document the haemodynamic significance of modest iliac disease demonstrated on arteriography, as it is clear that the mere presence of atheromatous changes in the aortoiliac system does not necessarily mandate correction prior to infrainguinal revascularisation. It is well know that this is best accomplished by measurement of systolic pressure gradients across the diseased segment during the arteriographic examination. A resting peak systolic gradient of ≥ 10 mm/Hg, or decrease of pressure $\geq 15\%$ of initial values following pharmacologic vasodilatation, signifies a significant obstruction that in most cases needs to be corrected before any distal procedure is done.

The use of iliac PTA prior to required distal procedures will obviously have the greatest potential advantage and appeal in elderly or high-risk patients with multilevel disease and severe ischaemic symptoms. In such patients, the safety and expediency of providing inflow by PTA for a necessary infrainguinal operation is more likely to outweigh any potential disadvantage of long-term durability.

Results

Complications

In reports of isolated iliac PTA procedures, major complications have been noted in approximately 5–10% of cases, and the procedure may not be successful (technical inability to dilate the lesion or lack of haemodynamic improvement) in 10–15% of patients.[9, 12, 13] As would be anticipated, experience described in series of combined PTA and surgery are similar. In our review, a major complication of iliac PTA occurred in five (6.3%) procedures.[14] In four of the five cases, these problems could be successfully corrected through a groin incision, and the planned distal surgical revascularisation procedure then carried out. Hence the original management plan was not significantly altered. Other reports of the combined procedures document the general safety of iliac PTA prior to distal surgery in appropriate situations.

Graft patency and limb salvage

The issue of whether or not correction of iliac disease by PTA as contrasted to conventional surgical treatment will provide a reliable and durable inflow source for a distal bypass is of crucial importance. Many earlier reports of combined treatment consisted of only small numbers of patients with brief follow-up. However, in recent years more long-term follow-up data has accumulated to more clearly establish the effectiveness and durability of iliac PTA as an inflow source in properly selected patients.

In our series, the overall 5-year primary patency of distal surgical procedures was 76% by life table analysis.[14] As expected, late patency varied depending upon the type of distal revascularisation. For instance, there were no failures of the small group of PTA/profundaplasty, and only two of the 18 femorofemoral grafts occluded during follow-up. Femorodistal grafts had a 5-year cumulative primary patency of 68% and secondary patency of 88%. Vein grafts performed better than prosthetic grafts (75% *vs.* 54% primary patency). For the 62 patients originally classified in the limb-threatened category, the 5-year cumulative limb salvage rate was 90%. Several other recent series have reported cumulative primary patency rates of distal grafts ranging from 67% to 91% at intervals of 3 to 5 years.[15–20] Thus, long-term function of distal surgical reconstructions are generally similar to those reported for infrainguinal grafts done in patients with normal inflow, particularly when it is recognised that a considerable number of distal grafts in most combined PTA/surgery series were prosthetic conduits.

Iliac restenosis

Most importantly, all series note that recurrent iliac disease (either restenosis at the PTA site or new lesions in non-dilated iliac artery segments) was rarely responsible for distal graft failure.[15, 17, 19–21] In our own study,[14] careful analysis revealed that only four failures (5% of procedures) were felt attributable to recurrent impaired inflow. Compromise of inflow led to distal graft thrombosis in three of these patients, and haemodynamic failure (patent graft, recurrent symptoms) in one instance. Other series have similarly demonstrated that iliac restenosis, if detected early, may not always cause distal graft thrombosis, and in many instances may be successfully managed by simple redilation.

The reliability and durability of iliac inflow established by PTA should not be surprising. Many series of isolated iliac PTA have reported excellent long-term results for dilation of appropriately focal lesions.[8–12] Also, because only initially successful PTA will be followed by distal surgery, the 10–15% incidence of initial technical or haemodynamic failure of PTA is eliminated. Finally, the addition of an arterial reconstruction distal to a site of iliac balloon angioplasty will decrease peripheral resistance and increase blood flow across the iliac segment. There is evidence that this may result in dilatation of the donor iliac artery, thereby compensating for any possible restenosis of the PTA site, or otherwise retard progressive atherosclerosis in the donor iliac vessel in some fashion.[22] This has long been speculated upon for femorofemoral grafts.

Clinical outcome

A major advantage of combined treatment is the increased extent of revascularisation achieved when both levels of disease are corrected by combined PTA and distal surgery.

In our study group, mean pretreatment ankle/brachial index (ABI) of 0.31 ± 0.14 increased to 0.80 ± 0.16 after the combined procedures ($p < 0.0001$). The failure to more totally normalise the ABI reflects the impaired runoff status of some patients with infrainguinal bypass grafts or uncorrected distal disease in those patients undergoing femorofemoral bypass or profundaplasty alone. Nonetheless, this highly significant haemodynamic improvement was reflected by assessment of symptom relief. Overall, 90% of procedures resulted in marked or moderate improvement in preoperative symptoms. Of patients with claudication as their only complaint, 71% were totally relieved, while 24% were substantially improved. Relief of rest pain was achieved in 91% of patients in this category, while 86% of patients with ischaemic ulceration or limited distal gangrene had sufficient healing of necrotic lesions or local amputation to preserve the foot. There were no perioperative deaths. Such clinical results are definitely superior to those achieved with conventional treatment of multilevel disease by proximal surgical revascularisation alone.[3]

Remaining controversies

While the utility and durability of the combined treatments appears well established in properly selected patients, certain controversies remain.

Technique and timing of PTA

Almost all authors recommend the method of iliac PTA similar to that described by Gruntzig and Kumpe,[23] employing a balloon dilatation catheter inserted over a guidewire placed across the stenotic lesion under fluoroscopic control. While some authors have reported satisfactory results with a linear extrusion balloon catheter devised by Fogarty and associates for use without the need for a guidewire or

intraprocedural fluoroscopy,[24–26] it is generally agreed that such a "blind" PTA technique is more likely to result in a higher incidence of complications or particularly inadequate dilation. Irrespective of the method used for iliac PTA, a key principle is that the adequacy of dilatation of the lesion must be conclusively verified before proceeding with distal surgery. This is best documented by a combination of post-PTA contrast arteriography, as well as determination that the pre-PTA pressure gradient across the lesion has been adequately relieved.

More difference of opinion exists as to whether preliminary PTA should be performed as a separate procedure prior to the distal surgical operation, or done concomitantly with arterial reconstruction in the operating room itself. Some authors site the expediency and possible cost savings of doing both procedures at the same time in the operating room, and maintain that any complications of PTA can be immediately and readily corrected in this setting.[15, 19, 21, 26–28] However, it is my preference to perform iliac PTA one or more days before the operative procedure for several reasons. First, the imaging capabilities and availability of a variety of guidewires, catheters, and other ingredients essential to safe and effective performance of PTA are usually better in the angiography suite than in most operating rooms. Secondly, separation of the procedures allows repeat vascular laboratory evaluation and observation of the clinical benefit of initial PTA. In some cases, this may be sufficient and the distal surgical procedure not required. Most importantly, an interval of 24–48 hours or more allows accurate identification of the small number of patients who may have complications or an inadequate haemodynamic result of PTA. In this regard, it is important to recall that many large series of iliac PTA have reported a 5–15% incidence of technical failure.[8, 9, 12] This may be considerably more difficult to precisely determine in the operating room immediately prior to a distal operation.

Use of iliac stents

In recent years, use of intravascular stents as an adjunct to PTA has generated considerable interest.[29] Currently, the use of a stent would be considered appropriate by many authorities if the result of PTA is suspect on repeat contrast arteriography, particularly if a residual pressure gradient is still present. Definitive data is not presently available, however, to establish that stenting will allow more extensive iliac inflow disease or segmental total iliac occlusions to be reliably corrected prior to distal surgical procedures. Until such data exists, it seems prudent to base infrainguinal arterial reconstructions upon inflow established by iliac PTA of only localised lesions acknowledged to be well suited to conventional PTA.

Who should perform PTA?

Although combined procedures have been carried out in many series by a team approach, with interventional radiologists performing the iliac PTA, there is no reason that surgeons may not perform both procedures on their patients in either staged fashion or in the operating room in conjunction with the surgical procedure. It is obviously imperative, however, that for this to be successful the surgeon must be familiar and experienced with the technical aspects of PTA, adequately adept at guidewire and catheter manoeuvres, use appropriate imaging, and verify a haemodynamically satisfactory result of PTA by pre- and post-PTA pressure determinations, etc. With the increasing experience with a variety of endovascular treatment methods by many vascular surgeons in the operating room currently, it seems likely that these important prerequisites for performance of iliac PTA by surgeons will be satisfied to an increasing extent in the near future.

Conclusions

In selected patients with multilevel occlusive disease, a combination of iliac PTA and a distal surgical procedure represents a safe, effective and durable management alternative. Iliac disease must be limited in extent and therefore amenable to PTA. The haemodynamic success of PTA must be carefully verified prior to proceeding with distal operation. Although the two procedures may be done simultaneously in the operating room in certain circumstances, it is often advantageous to perform PTA as a separate preliminary procedure 24–48 hours before distal grafting. If properly performed, iliac PTA provides reliable inflow, and long-term patency of distal surgical procedures based upon such inflow is equivalent to similar reconstructions done in patients with unimpaired inflow. The combination of iliac PTA and infrainguinal surgical revascularisation reduces the extent of surgical intervention and increases the comprehensiveness of limb revascularisation. For such

reasons, it represents a valuable method of management for some patients with multilevel disease.

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